



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application

Frank AUSTRUP, et al.

Application Number: 09/744,866

Filed: April 2, 2001

Examiner: Stephen J. Rawlings

Group Art Unit: 1643

Confirmation No.: 5636

For: **CANCER CELLS FROM BODY FLUIDS CONTAINING CELLS,  
ISOLATION THEREOF AND AGENTS CONTAINING THE SAME**

**REPLY BRIEF PURSUANT TO 37 C.F.R. 41.43**

Commissioner for Patents  
P.O. Box 1450  
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Sir:

This is in reply to the Examiner's Answer of January 23, 2006.

The only issue raised in the final rejection of June 9, 2005 in rejecting the appealed claims (24 and 28) is whether the limitation in these claims of "wherein the disseminated tumor cells are not modified prior to screening by labeling, by attaching particles, by triggering aggregation, by triggering cluster formation, with antibodies, enzymes, lectins, other ligands, other receptors or cross linking agents or by fixing," meets the written description requirement of 37 C.F.R. 112, first paragraph.

In Applicant's view, consideration can be limited to whether the following language from page 13, lines 25-32, of the application as filed causes the claims to meet the written description requirement.

Serial Number: 09/744,866  
Attorney Docket: GIES3001

Furthermore it is also possible to modify the cancer cells in the cell suspension prior to the screening process, for example by labeling, by attaching particles, by triggering aggregation and/or cluster formation using, for example, suitable antibodies, enzymes, lectins, other ligands and/or receptors or crosslinking reagents, by fixing and by inducing other defined states.

One contention by the PTO has been that this language doesn't provide basis for a negative limitation.

It has been Applicant's contention that the language "it is also possible" teaches two alternatives, namely including one or more of "labeling, etc" or excluding "labeling, etc". Applicant has relied in Ex parte Holt, 19 U.S.P.Q.2d 1211 (Bd. App.1991) to support his position.

Since its Brief was filed, Applicant has uncovered additional pertinent very recent case law, namely Upsher-Smith Laboratories v. PamLab, 75 U.S.P.Q.2d 1213 (Fed Cir 2005). Upsher holds that a vitamin supplement that optionally includes an antioxidant is a disclosure both of a vitamin supplement that contains an antioxidant and also a disclosure of a vitamin supplement that does not (negative limitation) contain an antioxidant. Applicant contends that the words "it is also possible" in claims 24 and 28 are the equivalent of "optionally" (Upsher) so that Upsher is determinative that the PTO's contention that page 13, lines 25-32, does not included disclosure of the negative limitation, is flat out wrong.

The Examiner's Answer does not cite any case law which supports its contention that the language on page 13 of the application as filed does not support the negative limitation of claims 24 and 28.

The Examiner's Answer criticizes the proviso in claims 24 and 28 for not tracking exactly the language at page 13, lines 25-32, of the application. It is pointed out that the reason for the difference is that adaption was made to what is good claim language and "other defined states" was left out to obviate the possibility of an indefiniteness rejection. In any event, the written description requirement doesn't require applicant to recite in the claims all of what is at page 13, lines 25-32.

Moreover, if the language at page 13, lined 25-32, is satisfactory, why doesn't the Examiner propose allowance in return for Applicant agreeing to change the language in the claims exactly to what is at page 13, lines 25-32; this would be consistent with the Patent Office's announced policy of the attorney and Examiner cooperating to expedite allowance. Why is the Examiner wasting Applicant's time and that of the Board and setting up a scenario where patients may die if there is a delay in exploitation due to a delay in patent coverage and therefore a delay in obtaining financing when the implementation of the change the Examiner argued is the correct language, would avoid this.

The rest of the 24 pages of the Examiner's Answer in response to the six pages of substance of Applicant's main brief, is submitted to be a "red herring".

For example, the Examiner's Answer takes the position that Working Example 1 doesn't illustrate "no modification prior to screening" because it is stated in the present tense (Examiner's Answer, page 17). What does "tense" have to do with written description? The point is that following the words of

Serial Number: 09/744,866  
Attorney Docket: GIES3001

example 1 exactly (following words exactly is what the Examiner's Answer advocates in relation to page 13, lines 25-32, of the application) provides a process with no modification prior to screening meeting the negative limitation of claims 24 and 28.

Moreover, Applicant's Working Example 4 is in the past tense. The Examiner's Answer derogates said Example 4 for omitting Tables 1 and 2 (Examiner's Answer, page 18). This has nothing to do with the written description issue. In any event, said Tables 1 and 2 are set forth in the priority document.

The Examiner's Answer takes the position that Example 2 should count more than Examples 1 and 4 because other examples refer to it (Examiner's Answer, page 18). In reply, Applicant notes that no working examples are necessary to meet the written description requirement; page 13, lines 25-32, is sufficient. Additionally, Working Examples 1 and 4 meet the claims and claim 5 erroneously refers to Example 2 on its face, as Example 2 does not isolate disseminated tumor cells, rather Example 1 does.

The Examiner's Answer at page 19 points to the portion of Example 5 which states that the isolated tumor cells were unable to proliferate. This has nothing to do with written description even if there were negative implications to be drawn. But Example 5 is not inconsistent with operativity. This is because the cancer cells that were unable to proliferate were from a woman who had undergone anti-cancer therapy prior to isolation of the cells. Thus, if the cells

Serial Number: 09/744,866  
Attorney Docket: GIES3001

were unable to proliferate after isolation, they were also unable to proliferate before isolation, i.e., anti-cancer therapy was effective. To put it another way, cancer cells that did not proliferate *in vivo* (before isolation) and do not proliferate *in vitro* (after isolation) can reasonably be said to have remained unaltered from their original state.

It is submitted that none of the points raised in the Examiner's Answer are pertinent or even correct.

**Reversal is Requested**

Reversal of the written description rejection, is requested.

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Respectfully submitted,  
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